

Amendments to the Drawings:

The attached replacement drawing sheet makes changes to Fig. 2 and replaces the original sheet with Fig.2.

Attachment: Replacement Sheet

REMARKS

Claims 1, 2, 5–10, 13, and 14 are pending in this application. By this Amendment, the specification is amended by the attached substitute specification, claims 1, 5, 6, and 13 are amended, and Figure 2 is amended by a Replacement Sheet. Support for the amendments to the claims may be found, for example, in the claims and specification as originally filed. No new matter is added.

I. Personal Interview

The courtesies extended to Applicants' representative by Examiner Shay at the interview held January 23, 2007, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below and constitute Applicants' record of the interview.

II. Objections to the Drawings

The Office Action objects to the drawings "because the elements of Fig. 2 are not labeled with indicia indicative of their function." Although Applicants believe that such labels are not necessary, the attached replacement drawing sheet labels the elements with indicia indicative of their function, and replaces the original sheet with Fig. 2. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

The Office Action also objects to the drawings under 37 CFR § 1.83(a) for failing to show every feature of the invention specified in the claims. 37 CFR § 1.83(a) provides that an "applicant for a patent is required to furnish a drawing of his or her invention where necessary for the understanding of the subject matter sought to be patented." However, a drawing is not required for a filing date under 35 U.S.C. 111 and 113 if the application contains at least one process claim including the term "process" or "method" in its introductory phrase. *See* MPEP §608.02 III. All of the claims are process claims and include the term "method" in their introductory phrases. Applicants respectfully submit that because the claims are process

claims, and that drawings would not have been required for the application to obtain a filing date, it is improper to require drawings showing every feature specified in the claims. Further, any such drawings are not necessary in this case for a full understanding of the claimed invention, at least in view of the remaining detailed disclosure including the specification and drawings. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

III. Objections to the Specification

The Office Action objects to the specification for containing grammatical errors. A substitute specification is provided in response to the objection. The substitute specification contains no new matter and therefore is in compliance with 37 C.F.R §1.125(b). The substitute specification also complies with 37 C.F.R §1.125(c) in that it is submitted with markings showing all changes relative to the immediate prior version of the specification on record, i.e., the amendments to the specification filed with the October 2, 2002 Petition and Preliminary Amendment, and refiled on April 12, 2004.

The Examiner correctly points out that Table 1 on page 12 is inconsistent with itself. Upon examination of the Table on page 12, it appears that the results listed in the column labeled "Increased energy (%)" are off by a factor of 10. These values have been corrected in the substitute specification. Accordingly, withdrawal of the objections to the specification is respectfully requested.

IV. Amendment

The Office Action objects to the Amendment filed on June 19, 2006 under 35 U.S.C. §132(a) as introducing new matter into the Disclosure.

A. Claim 1

The Office Action alleges that claim 1, amended to recite, "...1-100 ~~m/cm~~²-mJ/cm² of the energy density and 1-1000 mJ/cm² of the energy output..." introduces new matter into the

disclosure of the invention. Applicants respectfully disagree. This amendment is supported by the original specification, for example, at paragraphs [0029] and [0031], which read:

[0029] No particular limitation is posed upon the density of the energy of the laser, either. However, it may be in a range of 1 to 100 mJ/cm², and preferably in a range of 30 to 80 mJ/cm². The reason for the above range is that if it is less than 1 mJ/cm², the cell wall cannot be sufficiently processed, whereas if it is more than 100 mJ/cm², the laser penetrates the cell membrane and largely damages the cell.

...

[0031] The output of the laser is preferably 1 to 1000 mJ/cm², more preferably 10 to 100 mJ/cm².

In light of the reasons discussed above, and as agreed upon in the Personal Interview, withdrawal of the objection to the previously filed Amendment is respectfully requested.

B. Claim 5

It is alleged that claim 5, amended to recite, "...irradiating the cell through a surface of the quartz glass ~~chip is~~ chip coated with a metal..." introduces new matter into the disclosure of the invention. By this amendment, claim 5 is now amended to recite, "The method set forth in claim 1, wherein ~~irradiating further includes irradiating the cell through~~ a surface of the quartz glass chip is coated with a metal." Accordingly, reconsideration and withdrawal of the objection are requested.

C. Claim 6

It is alleged that claim 6, amended to recite, "...passing the laser beam through the surface of the quartz glass chip coated with at least one metal..." introduces new matter into the disclosure of the invention. By this amendment, claim 6 is now amended to recite, "The method set forth in claim 5, wherein ~~irradiating further includes passing the laser beam through the surface of the quartz glass chip coated with~~ the metal is at least one metal selected from the group consisting of aluminum, platinum, gold, palladium, and oxides thereof." Accordingly, reconsideration and withdrawal of the objection are requested.

D. Claim 8

It is alleged that claim 8, amended to recite "...~~introducing a foreign~~ foreign matter..." introduces new matter into the disclosure of the invention. Applicants respectfully disagree. This amendment is supported by the original specification, for example, at paragraph [0034], which reads:

[0034] Under the above conditions, the laser beam is irradiated to bore a part of the cell membrane and/or the cell wall of the cell, so that a *foreign matter can be introduced* into the cell through the hole thus bored. Further, the cell can be converted to a protoplast or a spheroplast by cutting off or removing a part of or an entire part of the cell membrane and/or the cell wall of the cell. In the present invention, since the laser is irradiated upon the cell through the optical fiber, only a specific cell existing in a complicated tissue can be converted to a protoplast or a spheroplast, such a cell only can be transformed (emphasis added).

In light of the reasons discussed above, and as agreed upon in the Personal Interview, withdrawal of the objection to the previously filed Amendment is respectfully requested.

E. Claim 13

It is alleged that claim 13, amended to recite "...passing the laser gear through an inert gas..." introduces new matter into the disclosure of the invention. Claim 13 is now amended to recite: "The method set forth in claim 1, wherein ~~irradiating further includes passing the laser gear through an~~ the inert gas is selected from the group consisting of a nitrogen gas, an argon gas, and a helium gas." This amendment is supported by the original specification, for example, at page 4, lines 7-11, which reads:

In a still further preferred embodiment of the cell-processing method in the present invention, a hollow space of the optical fiber is filled with an inert gas.

In a still further preferred embodiment of the cell-processing method in the present invention, the inert gas is at least one gas selected from the group consisting of a nitrogen gas, an argon gas and a helium gas.

In light of the reasons discussed above, and as agreed upon in the Personal Interview, withdrawal of the objection to the previously filed Amendment is respectfully requested.

V. Rejection under 35 U.S.C. §112, First Paragraph

The Office Action rejects claims 1, 2, 5–10, 13, and 14 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

A. Written Description

Specifically, the Office Action asserts that the original disclosure and the disclosure as amended is silent on the following claimed features:

- "1-100 mJ/cm² of the energy density and 1-1000 mJ/cm² of the energy output"
- "irradiating the cell through a surface of the quartz glass chip coated with a metal"
- "passing the laser beam through the surface of the quartz glass chip coated with at least one metal"
- "introducing foreign matter"
- "passing the laser gear through an inert gas"

To provide written description for a claim, the specification as originally filed must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventors were in possession of the invention as claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Specifically, the Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in the specification a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

With respect to claims 5, 6, and 13, the claims have been amended as discussed above. Thus, it is believed that claims 5, 6, and 13 fully comply with the written description requirements of 35 U.S.C. §112, first paragraph.

As to the remaining claims, Applicants respectfully submit that the Examiner fails to provide any basis as to why a person skilled in the art would not recognize in the specification a description of the invention defined by the claims. If understood correctly, the Office Action asserts that the written description is inadequate because the elements listed are not found in the original disclosure, as also asserted by the Office Action's objection to the same claimed elements under 35 U.S.C. §132(a) as introducing new matter into the Disclosure. However, as discussed *supra*, each of the claimed elements are clearly found in the disclosure as originally filed.

B. Enablement

The Office Action asserts that "passing the laser gear through an inert gas" and "passing the laser beam through the surface of the quartz glass chip coated with at least one metal" are not enablingly described in the specification. By this amendment, claims 5, 6, and 13 are amended in light of the Examiner's comments in the Office Action and in the Personal Interview. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

C. Conclusion

Claims 1, 2, 5–10, 13, and 14 fully comply with the written description and enablement requirements of 35 U.S.C. §112, first paragraph. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

VI. Rejection under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 2, 5–10, 13, and 14 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention. Applicants respectfully traverse the rejection.

A. Claim 2

The Office Action asserts that "[c]laim 2 is indefinite as it appears to fail to further limit the claim from which it depends, as it is unclear how the particular wavelength used manipulatively affects any of the claimed steps, and therefore what further limitation is intended is unclear."

Applicants respectfully submit that the rejection under 35 U.S.C. §112, second paragraph, is improper. The MPEP provides the following guidance to determine whether a dependent claim is proper:

The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim.

A dependent claim does not lack compliance with 35 U.S.C. 112, fourth paragraph, *simply because there is a question as to (1) the significance of the further limitation added by the dependent claim, or (2) whether the further limitation in fact changes the scope of the dependent claim from that of the claim from which it depends.* The test for a proper dependent claim under the fourth paragraph of 35 U.S.C. 112 is whether the dependent claim includes every limitation of the claim from which it depends. The test is not one of whether the claims differ in scope. (Emphasis added).

See MPEP §608.01(n) I.

Claim 2 recites, "The method set forth in claim 1, wherein the living cell or the living tissue is irradiated with the laser beam at a wavelength of 500 nm or less." Claim 2 includes every limitation of claim 1. Claim 1 places no restriction as to the wavelength of the laser beam used. Claim 2 clearly limits the wavelength of the laser beam used. The significance of this limitation is not relevant. Claim 2 is a proper dependent claim.

In light of the reasons discussed above, and as agreed upon in the Personal Interview, reconsideration and withdrawal of the rejection are respectfully requested.

B. Claims 5 and 6

Claim 5 recites, "The method set forth in claim 1, wherein irradiating further includes irradiating the cell through a surface of the quartz glass chip coated with a metal." Claim 5 includes every limitation of claim 1. Claim 1 does not require any coating on the quartz glass chip. Claim 5 clearly limits claim 1 by requiring that the quartz glass chip be coated with a metal. The significance of this limitation is not relevant. Claim 5 is a proper dependent claim.

Claim 6 contains all of the limitations of claim 5, and further requires that only certain metals be coated on the quartz glass chip. The significance of this limitation is not relevant. Claim 6 is a proper dependent claim.

In light of the reasons discussed above, and as agreed upon in the Personal Interview, reconsideration and withdrawal of the rejections are respectfully requested.

C. Claim 7

Claim 7 recites: "The method set forth in claim 1, wherein irradiating is conducted with a laser selected from the group consisting of an YAG laser, an excimer laser, an Ar ion laser, a nitrogen laser and a nitrogen-excited laser." Claim 7 includes every limitation of claim 1. Claim 1 does not require a specific type of laser. Claim 7 clearly limits claim 1 by requiring a specific type of laser. The significance of this limitation is not relevant. Claim 7 is a proper dependent claim.

In light of the reasons discussed above, and as agreed upon in the Personal Interview, reconsideration and withdrawal of the rejection are respectfully requested.

D. Claims 8–10

The Office Action states that claim 8 is rejected under 35 U.S.C. §112, second paragraph, but fails to provide any reason for the rejection. Nevertheless, claim 8 recites: "The method set forth in claim 1, further comprising introducing foreign matter into the living cell and/or the living tissue through a laser-irradiated portion thereof after irradiating the living cell or the living tissue with the laser beam." Claim 8 includes every limitation of claim 1. Claim 8 clearly limits claim 1 by requiring a step not required by claim 1. The significance of this limitation is not relevant. Claim 8 is a proper dependent claim.

Claim 9 depends from claim 8 and includes every limitation of claim 8. Claim 9 clearly limits claim 8 by further specifying the types of foreign matter that are introduced into the cell. The significance of this limitation is not relevant. Claim 9 is a proper dependent claim.

Claim 10 depends from claim 9 and includes every limitation of claim 9. Claim 10 clearly limits claim 9 by further specifying the types of genetic material that are introduced into the cell. The significance of this limitation is not relevant. Claim 10 is a proper dependent claim.

In light of the reasons discussed above, and as agreed upon in the Personal Interview, reconsideration and withdrawal of the rejections are respectfully requested.

E. Claim 13

Claim 13 recites: "The method set forth in claim 1, wherein the inert gas is selected from the group consisting of a nitrogen gas, an argon gas, and a helium gas." Claim 13 includes every limitation of claim 1. Claim 13 clearly limits claim 1 by specifying the type of inert gas. The significance of this limitation is not relevant. Claim 13 is a proper dependent claim.

In light of the reasons discussed above, and as agreed upon in the Personal Interview, reconsideration and withdrawal of the rejection are respectfully requested.

F. Claim 14

Claim 14 recites: "The method set forth in claim 1, wherein irradiating further includes passing the laser beam through a hollow optical fiber coated with a metal." Claim 14 includes every limitation of claim 1. Claim 14 clearly limits claim 1 by specifying that the hollow optical fiber be coated with a metal. The significance of this limitation is not relevant. Claim 14 is a proper dependent claim.

In light of the reasons discussed above, and as agreed upon in the Personal Interview, reconsideration and withdrawal of the rejections are respectfully requested.

VII. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1, 2, 5–10, 13, and 14 under 35 U.S.C. §103(a) over U.S. Patent No. 5,586,982 to Abela ("Abela") in view of *Flexible hollow waveguides for delivery of excimer-laser light* by Matsuura et al. ("Matsuura") in further view of U.S. Patent No. 6,039,726 to Lewis et al. ("Lewis"). Applicants respectfully traverse the rejection.

Without conceding the propriety of the rejections, independent claim 1 is amended to more clearly recite various novel features of the claimed invention, with particular attention to the Examiner's comments made during the personal interview. Specifically, claim 1 is amended to clarify that a cell is irradiated "with a laser beam with 1-100 mJ/cm² of the energy density and 1-1000 mJ/cm² of the energy output." Support for the amendment may be found, for example, in the original specification at paragraph [0028].

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.

Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the applied references, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

None of the applied references, whether considered alone or in combination, disclose or suggest each and every feature recited in claim 1. Additionally, there is no suggestion or motivation found to combine the references.

Abela relates to a treatment apparatus and method for transfecting cells in vivo (*see* column 1, lines 18–21). Abela generally describes use of a laser beam delivered through a hollow optical fiber to porate cells to deliver a treatment agent. However, Abela fails to disclose the step "irradiating a living cell or a living tissue with a laser beam with 1-100 mJ/cm² of energy density output through a hollow optical fiber filled with an inert gas" and that "the cell is irradiated with the laser through reflection and condensing which are effected through a chip of quartz glass in which hydroxide groups have been introduced" as required by claim 1.

The Office Action relies upon Matsuura and Lewis to cure these deficiencies. Matsuura is relied upon for allegedly teaching the formation of hollow wave guides for delivery of excimer laser light, and for the use of an inert gas. However, Matsuura fails to disclose or suggest irradiating a living cell or living tissue with a laser beam with 1-100 mJ/cm² of energy density output, or the use of a laser that is reflected and condensed through a chip of quartz glass in which hydroxide groups have been introduced.

The Office action further relies upon Lewis for its alleged description of a wave guide with a tapered tip in a medical system for applying high-energy radiation. However, Lewis does not disclose "the use of a laser that is reflected and condensed through a chip of quartz

glass" as required by claim 1. A chip of quartz glass is not equivalent to a quartz fiber with a tapered tip.

Furthermore, Lewis relates to surgical lasers for use with ArF excimer laser beams to provide precise cuts during tissue removal in a gaseous environment without collateral damage to surrounding tissues (*see* column 1, lines 11–17). Lewis does not teach or suggest "irradiating a living cell or a living tissue with a laser beam with 1-100 mJ/cm² of energy density output through a hollow optical fiber filled with an inert gas." Rather, Lewis is directed specifically to excision or ablating (i.e. destroying) soft tissue (*see* column 4, lines 45–47). Lewis discloses that an energy fluence of about 250 to 350 mJ/cm² is required for the effective ablation of soft tissue (*see* column 4, lines 45–47) and an energy fluence of about 500 mJ/cm² is required for effective soft tissue cutting (*see* column 5, lines 24–26). These levels far exceed the 1-100 mJ/cm² required by claim 1, and such levels would destroy the cell (*see* Original Specification at paragraph [0029]).

The combination of references fails to teach or suggest each and every feature recited in claim 1. Accordingly, claim 1 would not have been rendered obvious by Abela, Matsuura, and Lewis. Claims 2, 5–10, 13, and 14 depend from claim 1 and, thus, also would not have been rendered obvious by Abela, Matsuura, and Lewis. Reconsideration and withdrawal of the rejection are respectfully requested.

VIII. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 2, 5–10, 13, and 14 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,


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JAO:JRB

Attachments:

Marked-up copy of the originally filed specification
Clean substitute specification
Replacement Sheet

Date: February 7, 2007

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